



## ANTARES PHARMA ANNOUNCES FDA APPROVAL OF PARTNER'S PRODUCT UTILIZING OUR QUICKSHOT AUTO INJECTOR

*AMAG Pharmaceuticals Makena® Subcutaneous Auto-Injector Approved To Reduce The Risk Of  
Preterm Birth In Certain At-Risk Women*

**EWING, NJ, February 14, 2018** -- Antares Pharma, Inc. (NASDAQ:ATRS) today announced the successful regulatory outcome of the Makena® subcutaneous auto injector collaboration with AMAG Pharmaceuticals (AMAG) (NASDAQ:AMAG). AMAG announced U.S. Food and Drug Administration (FDA) approval for their supplemental New Drug Application for Makena® (hydroxyprogesterone caproate injection) subcutaneous auto injector drug-device combination product, which was designed as a ready-to-administer treatment to reduce the risk of preterm birth in women who are pregnant with one baby and who spontaneously delivered one preterm baby in the past. This drug-device combination product utilizes the Antares Pharma QuickShot® device which was specifically developed to deliver a rapid injection of highly viscous drug products such as progesterone in oil, through a fine gauge nonvisible needle.

"Today's announcement represents the first FDA approval of a drug-device combination product utilizing our QuickShot auto injector. This first pass approval was made possible through an excellent working collaboration with our device team and the development group at AMAG," said Robert F. Apple, President and Chief Executive Officer of Antares Pharma. "The Makena QuickShot device was designed to enhance performance on the attributes we believe are most critical to healthcare providers and patient acceptance, including decreased time to administer and use of a shorter, thinner nonvisible needle for subcutaneous injection, while potentially providing an alternative to the existing intramuscular methods of administration. We look forward to our continuing partnership with AMAG as it transitions from development to a commercial supply relationship."

In September 2014, Antares Pharma entered into a license, development and supply agreement to develop a variation of our VIBEX® QuickShot® subcutaneous auto injector for use with Makena®. Under this arrangement, AMAG will manufacture and supply the drug product to Antares. Antares will manufacture the device and be responsible for the assembly and packaging of the final product which will be sold to AMAG at cost plus margin. AMAG is also responsible for commercialization and distribution of the final product. Antares will receive high single digit to low double digit royalties on net sales as well as sales milestones.

### **About Makena® (hydroxyprogesterone caproate injection)**

Makena is a progestin indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered <37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. **It is not intended for use in women with multiple gestations or other risk factors for preterm birth.**

Makena should not be used in women with any of the following conditions: blood clots or other blood clotting problems, breast cancer or other hormone-sensitive cancers, or history of these conditions;

unusual vaginal bleeding not related to the current pregnancy, yellowing of the skin due to liver problems during pregnancy, liver problems, including liver tumors, or uncontrolled high blood pressure. Before patients receive Makena, they should tell their healthcare provider if they have an allergy to hydroxyprogesterone caproate, castor oil, or any of the other ingredients in Makena; diabetes or prediabetes, epilepsy, migraine headaches, asthma, heart problems, kidney problems, depression, or high blood pressure.

In one clinical study, certain complications or events associated with pregnancy occurred more often in women who received Makena. These included miscarriage (pregnancy loss before 20 weeks of pregnancy), stillbirth (fetal death occurring during or after the 20th week of pregnancy), hospital admission for preterm labor, preeclampsia (high blood pressure and too much protein in the urine), gestational hypertension (high blood pressure caused by pregnancy), gestational diabetes, and oligohydramnios (low amniotic fluid levels).

Makena may cause serious side effects including blood clots, allergic reactions, depression, and yellowing of the skin and the whites of the eyes. The most common side effects of Makena include injection site reactions (pain, swelling, itching, bruising, or a hard bump), hives, itching, nausea, and diarrhea. The most common side effects reported with the Makena auto-injector use (and higher than with the Makena intramuscular injection) was injection site pain.

For additional product information, including full prescribing information, please visit [www.makena.com](http://www.makena.com).

### **About QuickShot® Auto Injector**

The proprietary QuickShot® auto injector is designed to allow rapid subcutaneous self-administration of highly viscous drugs in oil such as testosterone or progesterone and biologics using high spring pressure through a fine gauge needle. Conventional auto injectors, or even a vial, needle and syringe are not able to inject highly viscous drugs efficiently or as fast and easy as the QuickShot® device. The QuickShot® auto injector can also provide the patient with the ease and speed of self-administration, comfort and discretion.

### **About Antares Pharma**

Antares Pharma focuses on self-administered parenteral pharmaceutical products. The Company's product, OTREXUP® (methotrexate) injection for subcutaneous use, is approved in the U.S. for the treatment of adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. The Company's product Sumatriptan Injection USP, is approved in the U.S. for the acute treatment of migraine and cluster headache and is distributed by Teva Pharmaceutical Industries, Ltd. (Teva). Antares Pharma is also developing an investigational new drug, XYOSTED™, for the treatment of testosterone deficiency (hypogonadism). The Company filed a New Drug Application for XYOSTED™ and received a Complete Response Letter. The Company's technology platforms include VIBEX® disposable auto injectors and disposable multi-use pen injectors. Antares Pharma has license, development and supply agreements with Teva that include VIBEX® epinephrine, exenatide multi-dose pen, and teriparatide multi-dose pen. The Company also provides AMAG Pharmaceuticals with a subcutaneous QuickShot® auto injector for administering Makena® (**hydroxyprogesterone caproate injection**). For more information, visit [www.antareshpharma.com](http://www.antareshpharma.com).

### **SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

**This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to: the timing of the commercial launch of the Makena subcutaneous auto injector product in the U.S. and future market acceptance and revenue from the Makena subcutaneous auto injector product; the outcome of the Type A meeting with the U.S. Food and Drug Administration (FDA), the Company's ability to resolve the deficiencies identified by the FDA in the Complete**

Response Letter, the timeframe associated with such resolution and whether any such response will be accepted by the FDA, FDA approval of the Company's NDA for XYOSTED and future market acceptance and revenue for XYOSTED; successful completion of the transaction with Ferring International Center, S.A. and satisfaction of the various conditions in the Ferring asset purchase agreement and payment of the full purchase price; Teva's expectations about timing and approval of the VIBEX<sup>®</sup> epinephrine pen ANDA by the FDA and potential product launch of the same, the therapeutic equivalence rating thereof, and any future revenue from the same; FDA action with respect to Teva's Abbreviated New Drug Application ("ANDA") for the Teriparatide multi-dose pen and the timing and approval, if any, by the FDA of the same; FDA action with respect to Teva's ANDA for the Exenatide pen and the timing and approval, if any, by the FDA of the same; Teva's ability to successfully commercialize VIBEX<sup>®</sup> Sumatriptan Injection USP and the amount of revenue from the same;; continued growth of prescriptions and sales of OTREXUP<sup>®</sup>; the timing and results of research projects, clinical trials, and product candidates in development; actions by the FDA or other regulatory agencies with the respect to the Company's products or product candidates of its partners; continued growth in product, development, licensing and royalty revenue; the Company's ability to obtain financial and other resources for its research, development, clinical, and commercial activities and other statements regarding matters that are not historical facts, and involve predictions. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance, achievements or prospects to be materially different from any future results, performance, achievements or prospects expressed in or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terminology such as "may", "will", "should", "would", "expect", "intend", "plan", "anticipate", "believe", "estimate", "predict", "potential", "seem", "seek", "future", "continue", or "appear" or the negative of these terms or similar expressions, although not all forward-looking statements contain these identifying words. Additional information concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2016, and in the Company's other periodic reports and filings with the Securities and Exchange Commission. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to the Company on the date hereof, and the Company undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this press release, except as required by law.

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